



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5
77 WEST JACKSON BOULEVARD
CHICAGO, IL 60604-3590

MAR 29 2006

REPLY TO THE ATTENTION OF

(AE-17J)

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Hal Sprague
Abbott Laboratories
Legal Regulatory & Compliance
100 Abbott Park Road
Dept. 32RA, Bldg. AP6A-2NW
Abbott Park, Illinois 60064

Dear Mr. Sprague:

Enclosed is a file stamped Consent Agreement and Final Order (CAFO) which resolves violations at Abbott Laboratories' North Chicago facility, CAA Docket No. CAA-05-2006-0018. As indicated by the filing stamp on its first page, we filed the CAFO with the Regional Hearing Clerk on MAR 30 2006.

Pursuant to paragraph 80 of the CAFO, Abbott Laboratories must pay the civil penalty within 30 days of MAR 30 2006. Your check must display the case docket number, CAA-05-2006-0018, and the billing document number, 050306020.

Please direct any questions regarding this case to Catherine Garypie, Associate Regional Counsel, (312) 886-5825.

Sincerely yours,

Bonnie Bush, Acting Section Chief
Air Enforcement and Compliance Assurance Section (MI/WI)

Enclosure

Protecting the environment is everyone's responsibility. Help EPA fight pollution by reporting possible harmful environmental activity. To do so, visit EPA's website at <http://www.epa.gov/compliance/compliants/index.html>

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5**

IN THE MATTER OF:

Abbott Laboratories,

Respondent.

) **Docket No.** CAA-05-2006-0018
)
)
) **Proceeding to Assess a Civil**
) **Penalty under Section 113(d) of the**
) **Clean Air Act, 42 U.S.C. § 7413(d)**
)

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U.S. ENVIRONMENTAL
PROTECTION AGENCY
REGION 5

Consent Agreement and Final Order

Preliminary Statement

1. This is an administrative action commenced and concluded under Section 113(d) of the Clean Air Act (the Act), 42 U.S.C. § 7413(d), and Sections 22.1(a)(2), 22.13(b), and 22.18(b) of the *Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits* (Consolidated Rules) as codified at 40 C.F.R. Part 22 (2004).
2. Complainant is the Director of the Air and Radiation Division, United States Environmental Protection Agency, Region 5 (U.S. EPA).
3. Respondent is Abbott Laboratories (Abbott or Respondent), a corporation doing business in the State of Illinois.
4. Where the parties agree to settle one or more causes of action before the filing of a complaint, the administrative action may be commenced and concluded simultaneously by the issuance of a Consent Agreement and Final Order (CAFO). 40 C.F.R. § 22.13(b) (2004).

5. The parties agree that settling this action without the filing of a complaint or the adjudication of any issue of fact or law is in their interest and in the public interest.

6. Abbott consents to entry of this CAFO and the assessment of the specified civil penalty, and agrees to comply with the terms of the CAFO.

Jurisdiction and Waiver of Right to Hearing

7. Abbott admits the jurisdictional allegations in this CAFO, and neither admits nor denies the factual allegations and the alleged violations set out in this CAFO.

8. Abbott waives its right to request a hearing as provided at 40 C.F.R. § 22.15(c), any right to contest the allegations in this CAFO, and its right to appeal this CAFO.

Statutory and Regulatory Background

9. Under Section 112 of the Act, the Administrator of U.S. EPA promulgated the National Emission Standards for Organic Hazardous Air Pollutants for Equipment Leaks at 40 C.F.R. Part 63, Subpart H (Subpart H) and the National Emission Standards for Organic Hazardous Air Pollutants for Certain Processes Subject to the Negotiated Regulation for Equipment Leaks at 40 C.F.R. Part 63, Subpart I (Subpart I); the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Pharmaceutical Production at 40 C.F.R. Part 63, Subpart GGG (the Pharma-MACT); the NESHAP for Pesticide Active Ingredient Production at 40 C.F.R. Part 63, Subpart MMM (the Pesticide MACT); and EPA Reference Method 21 at 40 C.F.R. Part 60 Appendix A (Method 21).

10. Subparts H and I, both part of the Hazardous Organic NESHAP (the HON), were proposed on December 31, 1992 and became final on April 22, 1994. The owner or operator of an existing affected source under another subpart in 40 C.F.R. Part 63 that references Subpart H must be in compliance by the date specified in that subpart, as required under 40 C.F.R. § 63.161.

11. Subpart I, at 40 C.F.R. § 63.190(b), states that Subpart H applies to emissions of the designated organic HAP from the processes specified in paragraphs (b)(1) through (b)(6) of Section 63.190 that are located at a plant site that is a major source as defined in Section 112(a) of the Act.

12. Subpart I, at 40 C.F.R. § 63.190(b)(5), states that pharmaceutical production processes using carbon tetrachloride or methylene chloride are affected sources.

13. Subpart I, at 40 C.F.R. § 63.190(e)(2), states that existing sources shall be in compliance with Subpart H no later than October 24, 1994 for process units subject to Subpart I.

14. The Pharma-MACT was proposed on April 2, 1997 and became final on September 21, 1998. The owner or operator of an existing affected source must comply with the provisions of the Pharma-MACT no later than October 21, 2002, as required under 40 C.F.R. § 63.1250(f)(1).

15. The Pharma-MACT, at 40 C.F.R. § 63.1250(a)(1), defines an affected source as a pharmaceutical manufacturing operation that: a) manufactures a pharmaceutical product; b) is located at a plant site that is a major source as defined in Section 112(a) of the Act; and c) processes, uses, or produces HAPs.

16. The Pesticide MACT was proposed on November 10, 1997 and became final on June 23, 1999. The owner or operator of an existing affected source must comply with the provisions of the Pesticide MACT no later than December 23, 2003, as required under 40 C.F.R. § 63.1364(a)(1).

17. The Pesticide MACT, at 40 C.F.R. § 63.1360(a), defines an affected source as the facility-wide collection of pesticide active ingredient manufacturing process units (PAI process

units) that process, use, or produce HAP, including waste management systems, heat exchange systems, and cooling towers that are associated with the PAI process units, and are located at a plant site that is a major source, as defined in Section 112(a) of the Act.

18. The Leak Detection and Repair (LDAR) Provisions of the HON, Pharma-MACT, and Pesticide MACT apply to pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, surge control vessels, bottoms receivers, instrumentation systems, control devices, and closed-vent systems that are intended to operate in organic HAP service 300 hours or more during the calendar year, as stated under 40 C.F.R. §§ 63.160(a), 63.1255(a)(1), and 63.1363(a)(1), respectively.

19. The HON, at 40 C.F.R. § 63.161, the Pharma-MACT, at 40 C.F.R. § 63.1251, and the Pesticide MACT, at 40 C.F.R. § 63.1361, define equipment in organic HAP service as equipment that either contains or contacts a fluid that is at least 5% by weight of total organic HAPs.

20. The NESHAP general provisions, at 40 C.F.R. § 63.4(a)(1), state that no owner or operator subject to the provisions of Part 63 must operate any affected source in violation of the requirements of this part except under an applicable extension of compliance.

21. The HON, at 40 C.F.R. § 63.162(c), requires the owner or operator of a process unit to identify equipment subject to the LDAR Provisions such that it can be distinguished readily from equipment that is not subject.

22. The HON, at 40 C.F.R. § 63.161, defines a process unit as a chemical manufacturing process unit as defined in Subpart F of Part 63, a process subject to the provisions

of Subpart I of Part 63, or a process subject to another subpart in 40 C.F.R. Part 63 that references Subpart H.

23. The Pharma-MACT, at 40 C.F.R. § 63.1255(a)(7), requires the owner or operator of an affected source to identify equipment subject to the LDAR Provisions such that it can be distinguished readily from equipment that is not subject.

24. The HON, at 40 C.F.R. § 63.168(b), requires the owner or operator of a source subject to Subpart H to monitor all valves in gas/vapor and light liquid service subject to the LDAR Provisions at the intervals specified in Sections 63.168(c) and (d).

25. The HON, at 40 C.F.R. § 63.168(c), states that in Phases I and II, each valve shall be monitored quarterly.

26. The HON, at 40 C.F.R. §§ 63.168(a)(1)(i)(A), (B), and (C), defines Phase I, Phase II, and Phase III as beginning on the compliance date, beginning no later than one year after the compliance date, and beginning no later than 2½ years after the compliance date, respectively, for each group of existing process units at existing sources subject to the provisions of Subparts F or I of Part 63.

27. The Pharma-MACT, at 40 C.F.R. § 63.1255(e)(2), requires the owner or operator of an existing affected source to monitor all valves in gas/vapor and light liquid service subject to the LDAR Provisions by no later than one year after the compliance date.

28. The HON, at 40 C.F.R. § 63.174(a), requires the owner or operator of a process unit subject to Subpart H to monitor all connectors in gas/vapor and light liquid service subject to the LDAR Provisions at the intervals specified in Section 63.174(b).

29. The HON, at 40 C.F.R. § 63.174(b)(1), requires the owner or operator of an existing process unit within an existing source to monitor all connectors in gas/vapor and light liquid service subject to the LDAR provisions by no later than one year after the compliance date.

30. The HON, at 40 C.F.R. § 63.168(d)(2), requires the owner or operator of a process unit with less than 2% leaking valves to monitor each valve in gas/vapor and light liquid service subject to the LDAR Provisions once each quarter in Phase III.

31. The HON, at 40 C.F.R. § 63.163(b)(3), requires the owner or operator of a process unit subject to Subpart H to check by visual inspection each calendar week each pump in light liquid service subject to the LDAR Provisions for indications of liquids dripping from the pump seal.

32. The HON, at 40 C.F.R. § 63.173(b)(1), requires the owner or operator of a source subject to Subpart H to check by visual inspection each calendar week each agitator in gas/vapor and light liquid service subject to the LDAR Provisions for indications of liquids dripping from the agitator.

33. The Pharma-MACT, at 40 C.F.R. § 63.1255(c)(2)(iii), requires the owner or operator of a source subject to Section 63.1255 to check by visual inspection each calendar week each pump in light liquid service and agitator in gas/vapor and light liquid service subject to the LDAR Provisions for indications of liquids dripping from the pump or agitator seal.

34. The HON, at 40 C.F.R. § 63.168(b)(1), requires the owner or operator of a source subject to Subpart H to monitor valves in gas/vapor and light liquid service subject to the LDAR Provisions by the method specified in Section 63.180(b) of Subpart H.

35. The Pharma-MACT, at 40 C.F.R. § 63.1255(e)(3)(i), requires the owner or operator of a source subject to Section 63.1255 to monitor valves in gas/vapor and light liquid service subject to the LDAR Provisions by the method specified in Section 63.180(b) of Subpart H.

36. The HON, at 40 C.F.R. § 63.174(a)(1), requires the owner or operator of a process unit subject to Subpart H to monitor connectors in gas/vapor and light liquid service subject to the LDAR Provisions by the method specified in Section 63.180(b) of Subpart H.

37. The HON, at 40 C.F.R. § 63.163(b)(1), requires the owner or operator of a process unit subject to Subpart H to monitor each pump in light liquid service subject to the LDAR Provisions monthly to detect leaks by the method specified in Section 63.180(b) of Subpart H.

38. The HON, at 40 C.F.R. § 63.173(a)(1), requires the owner or operator of a source subject to Subpart H to monitor each agitator in gas/vapor and light liquid service subject to the LDAR Provisions monthly to detect leaks by the method specified in Section 63.180(b) of Subpart H.

39. The Pharma-MACT, at 40 C.F.R. § 63.1255(c)(2)(i), requires the owner or operator of a source subject to Section 63.1255 to monitor each pump in light liquid service and agitator in gas/vapor and light liquid service subject to the LDAR Provisions quarterly to detect leaks by the method specified in Section 63.180(b) of Subpart H.

40. The HON, at 40 C.F.R. § 63.180(b)(1), requires the owner or operator of an affected source subject to Subpart H to comply with the monitoring procedures and requirements of Method 21.

41. Method 21, at 40 C.F.R. Part 60, Appendix A, Section 8.3.1, requires the owner or operator of an affected source to slowly sample the interface of a component where leakage is indicated until the maximum meter reading is obtained.

42. The Pharma-MACT, at 40 C.F.R. § 63.1258(h)(2)(iii)(A), requires the owner or operator of fixed roof vapor suppression equipment with a capacity greater than 0.42m³ to conduct an initial inspection according to the procedures in Section 63.1258(h)(3).

43. The Pharma-MACT, at 40 C.F.R. § 63.1258(h)(3)(i), states that inspections shall be conducted in accordance with Method 21.

44. The Pharma-MACT, at 40 C.F.R. § 63.1258(b)(1)(iv)(A)(4), requires the owner or operator of an affected source to establish the minimum regeneration steam flow rate under worst-case conditions for each regenerative carbon adsorber.

45. The Pharma-MACT, at 40 C.F.R. § 63.1258(b)(8), states that exceedances of parameters monitored according to the provisions of paragraph (b)(1)(iv), and excursions as defined by paragraphs (b)(7)(i) through (iii), constitute violations of the operating limit.

46. The Administrator of U.S. EPA (the Administrator) may assess a civil penalty of up to \$27,500 per day of violation up to a total of \$220,000 for NESHAP violations that occurred from January 31, 1997 through March 15, 2004, and may assess a civil penalty of up to \$32,500 per day of violation up to a total of \$270,000 for violations that occurred after March 15, 2004 under Section 113(d)(1) of the Act, 42 U.S.C. § 7413(d)(1), and 40 C.F.R. Part 19 (2004).

47. Section 113(d)(1) of the Act limits the Administrator's authority to matters where the first alleged date of violation occurred no more than 12 months prior to initiation of the administrative action, except where the Administrator and the Attorney General of the United

States jointly determine that a matter involving a longer period of violation is appropriate for an administrative penalty action.

48. The Administrator and the Attorney General of the United States, each through their respective delegates, have determined jointly that an administrative penalty action is appropriate for the period of violations alleged in this CAFO.

Factual Allegations

49. Abbott owns and operates a health care products manufacturing plant site at 1401 Sheridan Road, North Chicago, Illinois.

50. At the North Chicago plant site, Buildings R-5, R-6, and R-6C, along with Tank Farm Areas S-7, S-30, and S-32, contain pharmaceutical production process units that used carbon tetrachloride and/or methylene chloride between October 24, 1994 and October 21, 2002.

The North Chicago plant site also has been a major source, as defined in Section 112(a) of the Act, since before October 24, 1994. Therefore, prior to October 21, 2002, Abbott was an affected source subject to the LDAR Provisions of the HON.

51. At the North Chicago plant site, Buildings C-10, R-5, R-6, R-6C, R-7A, and R-10, along with Tank Farm Areas S-7, S-30, and S-32, contain manufacturing operations that have produced a pharmaceutical product and have been processing, producing, or using organic HAP since October 21, 2002. As noted in paragraph 50 above, the North Chicago plant site also has been a major source, as defined in Section 112(a) of the Act, since before October 24, 1994. Therefore, as of October 21, 2002, Abbott has been an affected source subject to the LDAR Provisions of the Pharma-MACT.

52. At the North Chicago plant site, Building R-2B contains manufacturing operations that had produced a pharmaceutical product and had processed, produced, or used organic HAP from October 21, 2002 through June 30, 2005. During this period, Building R-2B was subject to the LDAR Provisions of the Pharma-MACT.

53. At the North Chicago plant site, Buildings R-3 and R-10 contain PAI process units that have been processing, using, or producing organic HAP. As noted in paragraph 50 above, the North Chicago plant site also has been a major source, as defined in Section 112(a) of the Act, since before October 24, 1994. Therefore, as of December 23, 2003, Abbott has been an affected source subject to the LDAR Provisions of the Pesticide MACT.

54. U.S. EPA inspected the North Chicago plant site on June 22-24, 2004. U.S. EPA also issued an Information Request to Abbott on July 22, 2004. Abbott responded to the Information Request on August 31, 2004 and submitted updated information on December 9, 2004 and January 10, 2005.

55. Abbott did not identify 93 components (summarized in Table A) as subject to the LDAR Provisions until August 18, 2004, when it allegedly discovered that it had incorrectly identified these components as being exempt from the LDAR Provisions of the HON and the Pharma-MACT.

Table A.

	R-5	R-6	R-6C	R-10	S-30	S-32
Valves	8	3	5	1	9	0
Connectors	1	15	17	8	20	5
Pressure-relief devices	0	1	0	0	0	0

56. Prior to August 2004, Abbott never monitored the valves and connectors referenced in Table A.

57. Abbott never found more than 2% of valves in a process group to be leaking from July 1999 through October 2002, although there were some quarters during this time when the equipment was not in organic HAP service, as shown in Table B.

Table B.

	R-5	R-6	R-6C	S-30
3 rd quarter 1999	In service	In service	In service	In service
4 th quarter 1999	In service	In service	In service	In service
1 st quarter 2000	Down	Down	Down	Down
2 nd quarter 2000	In service	In service	In service	In service
3 rd quarter 2000	In service	In service	In service	In service
4 th quarter 2000	In service	In service	Down	Down
1 st quarter 2001	In service	In service	In service	In service
2 nd quarter 2001	Down	In service	In service	In service
3 rd quarter 2001	Down	In service	Down	In service
4 th quarter 2001	In service	In service	Down	Down
1 st quarter 2002	In service	In service	Down	In service
2 nd quarter 2002	In service	In service	In service	In service
3 rd quarter 2002	In service	In service	In service	In service
4 th quarter 2002	In service	In service	In service	In service

58. Abbott found less than 0.25% of valves leaking during its initial monitoring survey for the Pharma-MACT.

59. Abbott failed to visually inspect six pumps in R-2B the week of January 18, 2004, a pump in S-7 the weeks of January 12, 2003 through September 19, 2004, and four agitators in R-5 the weeks of July 1, 1999 through September 13, 2004.

60. An LDAR technician monitored 1318, 1083, 2652, 2087, 1016, 1881, 1140, and 1140 components on August 5, 1999, August 11, 1999, September 8, 1999, June 12, 2000, September 7, 2000, April 15, 2003, August 8, 2003 and September 3, 2003, respectively.

61. Abbott uses 200-300 gallon totes to transport wastewater from the manufacturing area of a process to on-site holding tanks.

62. Abbott did not inspect the totes per Method 21 until August 2004.

63. Abbott owns and operates a regenerative carbon adsorber subject to the Pharma-MACT in Area S-32.

64. On October 7, 2002, Abbott conducted a performance test on the S-32 carbon adsorber and verified that a regeneration steam flow rate of at least 5419 lbs/hr will regenerate the carbon beds to maintain a 98% efficiency for control of methylene chloride emissions.

65. Abbott tracked the regeneration steam flow rate of the S-32 carbon adsorber against an established minimum flow rate of 4877 lbs/hr from October 2002 until February 2004.

66. According to a Periodic Report submitted to the U.S. EPA on May 13, 2004, there were 30 instances from December 21, 2003 to March 20, 2004 when the bed regeneration frequency for the S-32 carbon adsorber was below the minimum limit of 51 minutes.

67. According to Periodic Reports submitted to the U.S. EPA on November 14, 2003, February 11, 2004, and May 13, 2004, there were 14 instances from March 20, 2003 to September 20, 2003, 7 instances from September 21, 2003 to December 20, 2003, and 4 instances from December 21, 2003 to March 20, 2004 when the pH for scrubber SC-5003 in Building C-10 was below the minimum limit.

68. On December 22, 2004, U.S. EPA issued a Finding of Violation to Abbott.

Alleged Violations

69. As set forth above, Abbott failed to identify equipment subject to the LDAR Provisions such that it can be distinguished from equipment that is not subject, constituting a violation of 40 C.F.R. § 63.162(c), 40 C.F.R. § 63.1255(a)(7), and Section 112 of the Act, 42 U.S.C. § 7412.

70. As set forth above, Abbott failed to monitor all valves and connectors in gas/vapor and light liquid service subject to the LDAR Provisions by October 24, 1994 and October 24, 1995, respectively, under the HON, and by October 21, 2003 under the Pharma-MACT, constituting a violation of 40 C.F.R. § 63.168(b), 40 C.F.R. § 63.168(c), 40 C.F.R. § 63.1255(e)(2), 40 C.F.R. § 63.174(a), 40 C.F.R. § 63.174(b)(1), and Section 112 of the Act, 42 U.S.C. § 7412.

71. As set forth above, Abbott failed to monitor all valves in gas/vapor and light liquid service subject to the LDAR Provisions quarterly under the HON, constituting a violation of 40 C.F.R. § 63.168(b), 40 C.F.R. § 63.168(d)(2), and Section 112 of the Act, 42 U.S.C. § 7412.

72. As set forth above, Abbott failed to check by visual inspection each calendar week all pumps in light liquid service and agitators in gas/vapor and light liquid service subject to the LDAR Provisions, constituting a violation of 40 C.F.R. § 63.163(b)(3), 40 C.F.R. § 63.173(b)(1), 40 C.F.R. § 63.1255(c)(2)(iii), and Section 112 of the Act, 42 U.S.C. § 7412.

73. As set forth above, Abbott failed to monitor equipment subject to the LDAR Provisions per Method 21, constituting a violation of 40 C.F.R. § 63.168(b)(1), 40 C.F.R. § 63.1255(e)(3)(i), 40 C.F.R. § 63.174(a)(1), 40 C.F.R. § 63.163(b)(1), 40 C.F.R. § 63.173(a)(1), 40 C.F.R. § 63.1255(c)(2)(i), 40 C.F.R. § 63.180(b)(1), Method 21 at 40 C.F.R. Part 60, Appendix A, Section 8.3.1, and Section 112 of the Act, 42 U.S.C. § 7412.

74. As set forth above, Abbott failed to inspect vapor suppression equipment in accordance with Method 21 until August 2004, constituting a violation of 40 C.F.R. § 63.1258(h)(2)(iii)(A), 40 C.F.R. § 63.1258(h)(3)(i), and Section 112 of the Act, 42 U.S.C. § 7412.

75. As set forth above, Abbott failed to establish the correct minimum regeneration steam flow rate for the S-32 carbon adsorber, constituting a violation of 40 C.F.R. § 63.1258(b)(1)(iv)(A)(4) and Section 112 of the Act, 42 U.S.C. § 7412.

76. As set forth above, Abbott failed to keep the regeneration frequency of the S-32 carbon adsorber above the established minimum value, constituting a violation of 40 C.F.R. § 63.1258(b)(8) and Section 112 of the Act, 42 U.S.C. § 7412.

77. As set forth above, Abbott failed to keep the pH of scrubber SC-5003 above the established minimum value, constituting a violation of 40 C.F.R. § 63.1258(b)(8) and Section 112 of the Act, 42 U.S.C. § 7412.

Civil Penalty

78. Pursuant to Section 113(e) of the Act, 42 U.S.C. § 7413(e), in determining the amount of the penalty assessed, U.S. EPA took into account (in addition to such other factors as justice may require) the size of Abbott's business, the economic impact of the penalty on Abbott's business, Abbott's full compliance history and good faith efforts to comply, the duration of the violations, payments by Abbott of penalties previously assessed for the same violations, the economic benefit of noncompliance, and the seriousness of the violations.

79. Based on an analysis of the above factors, including Abbott's cooperation, prompt return to compliance, and agreement with the U.S. EPA to perform the Supplemental Environmental Projects (SEPs) set out below, U.S. EPA has determined that an appropriate civil penalty to settle this action is \$57,372.

80. Abbott must pay the \$57,372 civil penalty by cashier's or certified check payable to the "Treasurer, United States of America," in accordance with paragraphs 81 and 82 below, within 30 days after the effective date of this CAFO.

81. Abbott must send the check to:

U.S. Environmental Protection Agency
Region 5
P.O. Box 70753
Chicago, Illinois 60673

82. A transmittal letter, stating Respondent's name, complete address, the case docket number, and the billing document number must accompany the payment. Respondent must write the case docket number and the billing document number on the face of the check. Respondent must send copies of the check and transmittal letter to:

Attn: Regional Hearing Clerk, (E-19J)
U.S. Environmental Protection Agency, Region 5
77 West Jackson Blvd.
Chicago, Illinois 60604-3511

Attn: Compliance Tracker, (AE-17J)
Air Enforcement and Compliance Assurance Branch
Air and Radiation Division
U.S. Environmental Protection Agency, Region 5
77 West Jackson Blvd.
Chicago, Illinois 60604-3511

Catherine Garypie, (C-14J)
Office of Regional Counsel
U.S. Environmental Protection Agency, Region 5
77 West Jackson Blvd.
Chicago, Illinois 60604-3511

83. This civil penalty is not deductible for federal tax purposes.

84. If Abbott does not pay timely the civil penalty, or any stipulated penalties due under paragraph 99 below, U.S. EPA may bring an action to collect any unpaid portion of the penalty with interest, handling charges, nonpayment penalties, and the United States' enforcement expenses for the collection action under Section 113(d)(5) of the Act, 42 U.S.C. § 7413(d)(5). The validity, amount, and appropriateness of the civil penalty are not reviewable in a collection action.

85. Interest will accrue on any overdue amount from the date payment was due at a rate established under 31 U.S.C. § 3717. Abbott will pay a \$15 handling charge each month that any portion of the penalty is more than 30 days past due. Abbott will pay a quarterly nonpayment penalty each quarter during which the assessed penalty is overdue according to Section 113(d)(5) of the Act, 42 U.S.C. § 7413(d)(5). This nonpayment penalty will be 10 percent of the aggregate

amount of the outstanding penalties and nonpayment penalties accrued from the beginning of the quarter.

Supplemental Environmental Projects

86. Abbott agrees to complete two SEPs designed to protect the environment and public health by reducing fugitive emissions of HAPs from its North Chicago facility through an enhanced LDAR program and by reducing criteria air pollutants through a hybrid vehicle project.

87. At its North Chicago facility, Abbott must perform the enhanced LDAR SEP as follows:

- a. **More Frequent Monitoring.** Abbott shall perform LDAR monitoring for valves, connectors, pumps, and agitators in HAP service more frequently than required under the LDAR Provisions for a period of two (2) years, beginning on July 1, 2006.
 - i. Abbott shall monitor all valves quarterly, all connectors semi-annually, and all pumps and agitators monthly;
 - ii. Abbott shall perform LDAR monitoring per Method 21 and report the results per applicable Pharma-MACT and Pesticide MACT regulations and per the requirements of this CAFO;
 - iii. Abbott shall utilize a Toxic Vapor Analyzer 1000B Flame Ionization Detector (FID) equipped with a data logger that automatically records the emission levels detected at each component, the date and time each sample is taken, and the monitoring instrument and technician identification numbers. (If an equivalent or superior data recording instrument becomes available, Abbott may request approval to use such instrument.);
 - iv. Abbott may allow the LDAR monitoring to be performed by an outside contractor;
 - v. Abbott shall submit a schedule of the monitoring events to U.S. EPA and may modify the schedule with at least two days advance written notice to U.S. EPA.

b. More Stringent Leak Repair Standard. Abbott shall utilize a reduced leak "repair action level" standard (below the regulatory leak definition) for valves, connectors, pumps, and agitators as follows: 250 ppm for valves and connectors, 500 ppm for pumps, and 2000 ppm for agitators. These leak levels will trigger repair as described in the Pharma-MACT and Pesticide MACT regulations but are not otherwise applicable for regulatory purposes.

c. Upgrading Components – New Technology.

i. Abbott shall, as a "first option" for repair of leaking components, evaluate upgrading valves, connectors, pumps, and agitators to utilize improved technology, or environmentally enhanced alternatives or processes or technology, to provide improved pollution prevention (such as audits for short-bolting, or other improvements for the different types of components). Abbott shall document each evaluation with details regarding conclusions reached and actions taken;

ii. Abbott shall evaluate upgrading leaking or even non-leaking pumps to either double mechanical seal pumps or seal-less pumps (meeting the requirements of the Pharma-MACT or the Pesticide MACT) to eliminate the need for monitoring these components and to reduce fugitive emissions from them. Abbott shall document each evaluation with details regarding conclusions reached and actions taken;

iii. Abbott shall evaluate more aggressive alternatives as part of a "first attempt" on repair of leaks, such as, for example, "drill and tap" repair technology for valves where there is no risk of product contamination, process interference, equipment damage, explosion, or other hazard or adverse reaction such that the valve would not be placed on the delay of repair list. Abbott shall document each evaluation with details regarding conclusions reached and actions taken.

d. Root-Cause Analysis. Abbott shall, within one year from the date the CAFO is filed, perform an engineering analysis on monitoring results beginning in January 2004, to determine potential "root causes" and sources of leaks, evaluating at a minimum the following:

i. Trends in leaks due to component service (gas, vapor, etc.), process conditions (temperature, pressure, vibrational movement, etc.), and material compatibility issues;

ii. Trends in leaks due to equipment type and/or manufacturer.

e. Prevention of Component Leaks. Abbott shall develop a maintenance and corrective action program, incorporating the results of the Root-Cause Analysis, including processes or technologies that provide improved prevention measures.

f. Internal Quality Assurance (QA)/Quality Control (QC) Audit Procedure. Abbott shall establish guidelines and procedures to audit its LDAR program on a biannual basis. These QA/QC procedures should include, but are not limited to, the following:

- i. Identifying components that are required to be in the LDAR program;
- ii. Ensuring all components in the LDAR program were monitored in the appropriate frequency;
- iii. Spot checking of LDAR personnel while conducting LDAR monitoring in the field;
- iv. Reviewing all repair records for first attempts to be made within five days and final repairs within fifteen days;
- v. Ensuring proper documentation and sign-offs have been put in place for all equipment placed on shutdown or delay of repair;
- vi. Reviewing monitoring data and component counts (monitored components per day) for feasibility;
- vii. Making sure proper calibration records and organic analyzer maintenance data is stored.

g. Reporting. Abbott shall provide U.S. EPA with Annual Reports that describe steps Abbott is taking to maintain and ensure compliance with the requirements of the applicable regulations and this CAFO. Abbott shall submit the Annual Reports on October 1, 2007 and October 1, 2008 with the following information:

- i. The results of the LDAR monitoring, including individual monitoring data (preferably in electronic form), enhanced monitoring, and repair programs;
- ii. A description of the equipment leaks detected during the year and reviewed under the Root Cause Analysis, and the steps taken to correct them;

iii. A summary of any improvements to the monitoring program that Abbott's experience indicates might be helpful in identifying, preventing, reducing, and/or repairing equipment leaks;

iv. Documentation of all leak evaluations under the monitoring and repair program conducted during the year.

88. Abbott must spend at least \$259,300 on the enhanced LDAR SEP.

89. Abbott must submit a SEP completion report for the enhanced LDAR project to U.S. EPA by December 31, 2008. This report must contain the following information:

- a. Detailed description of the SEP as completed;
- b. Description of any operating problems and the actions taken to correct the problems;
- c. Itemized costs of goods and services used to complete the SEP documented by copies of invoices, purchase orders, or cancelled checks that specifically identify and itemize the individual costs of the goods and services;
- d. Certification that Abbott has completed the SEP in compliance with this CAFO;
- e. Description of the environmental and public health benefits resulting from the SEP (quantify the benefits and pollution reductions, if feasible).

90. Abbott agrees to complete the hybrid vehicle SEP by replacing 27 of its Jeep Liberty Sport sales vehicles, including vehicles affiliated with Abbott facilities in the Great Lakes Airshed, with Ford Escape Hybrid vehicles no later than December 31, 2006 and continuously use each hybrid vehicle for at least 37 months.

91. Abbott must spend at least \$159,000 for the hybrid vehicle SEP.

92. Abbott must submit a SEP completion report for the hybrid vehicle project to U.S. EPA within one year of the effective date of this CAFO. This report must contain the following information:

- a. Detailed description of the SEP as completed;
- b. Description of any operating problems and the actions taken to correct the problems;
- c. Itemized costs of goods and services used to complete the SEP documented by copies of invoices, purchase orders, or cancelled checks that specifically identify and itemize the individual costs of the goods and services;
- d. Certification that Abbott has completed the SEP in compliance with this CAFO;
- e. Description of the environmental and public health benefits resulting from the SEP (quantify the benefits and pollution reductions, if feasible).

93. Abbott certifies that it is not required to perform or develop either the enhanced LDAR SEP or the hybrid vehicle SEP by any law, regulation, grant, order, or agreement, or as injunctive relief as of the date it signs this CAFO. Abbott further certifies that it has not received, and is not negotiating to receive, credit for the SEPs in any other enforcement action.

94. U.S. EPA may inspect the facility at any time to monitor Abbott's compliance with this CAFO's SEP requirements.

95. Abbott must submit all notices and reports required by this CAFO by first class mail to:

Attn: Compliance Tracker (AE-17J)
 Air Enforcement and Compliance Assurance Branch
 Air and Radiation Division
 U.S. Environmental Protection Agency, Region 5
 77 West Jackson Blvd.
 Chicago, Illinois 60604-3511

96. In each report that Abbott submits as provided by this CAFO, it must certify that the report is true and complete by including the following statement signed by a responsible corporate official or an authorized designee:

I certify that I am familiar with the information in this document and that, based on my inquiry of those individuals responsible for obtaining the information, the information is true and complete to the best of my knowledge. I know that there are significant penalties for submitting false information, including the possibility of fines and imprisonment for knowing violations.

97. Following receipt of the SEP completion reports described in paragraphs 89 and 92 above, U.S. EPA will notify Abbott in writing within 30 days of receipt of each report that:

- a. It has satisfactorily completed the SEP and the SEP report;
- b. There are deficiencies in the SEP as completed or in the SEP report and U.S. EPA will give Abbott 30 days to correct the deficiencies; or
- c. It has not satisfactorily completed the SEP or the SEP report, and U.S. EPA will seek stipulated penalties under paragraph 99 below.

98. If U.S. EPA exercises option b. above, Abbott may object in writing to the deficiency notice within 10 days of receiving the notice. The parties will have 30 days from U.S. EPA's receipt of Abbott's objection to reach an agreement. If the parties cannot reach an agreement, U.S. EPA will give Abbott a written decision on its objection. Abbott will comply with any requirements that U.S. EPA imposes in its decision. If Abbott does not complete the

SEP as required by U.S. EPA's decision, Abbott will pay stipulated penalties to the United States under paragraph 99 below.

99. If Abbott violates any requirement of this CAFO relating to the SEPs, Abbott must pay stipulated penalties to the United States as follows:

- a. If Abbott fails to complete the enhanced LDAR SEP in a timely manner, as required by this CAFO, including spending at least 90% of the amount specified in paragraph 88 above to implement the SEP, Abbott must pay a stipulated penalty in the amount of \$750,000;
- b. If Abbott fails to complete the hybrid vehicle SEP in a timely manner, as required by this CAFO, including spending at least 90% of the amount specified in paragraph 91 above to implement the SEP, Abbott must pay a stipulated penalty in the amount of \$480,000.

100. U.S. EPA's determinations of whether Abbott satisfactorily completed each SEP and whether it made good faith, timely efforts to complete each SEP will bind Abbott.

101. Abbott must pay any stipulated penalties within 15 days of receiving U.S. EPA's written demand for the penalties. Abbott will use the method of payment specified in paragraphs 81 and 82, above, and will pay interest, handling charges, and nonpayment penalties on any overdue amounts.

102. Any public statement that Abbott makes referring to the SEPs must include the following language, "Abbott undertook this project under the settlement of the United States Environmental Protection Agency's enforcement action against Abbott for alleged violations of Clean Air Act requirements regarding equipment standards and monitoring for equipment leaks."

103. If an event occurs that causes or may cause a delay in completing a SEP as required by this CAFO:

a. Abbott must notify the U.S. EPA in writing within 10 days after learning of an event which caused or may cause a delay in completing the SEP. The notice must describe the anticipated length of the delay, its cause(s), Abbott's past and proposed actions to prevent or minimize the delay, and a schedule to carry out those actions. Abbott must take all reasonable actions to avoid or minimize any delay. If Abbott fails to notify U.S. EPA according to this paragraph, Abbott will not receive an extension of time to complete the SEP.

b. If the parties agree that circumstances beyond the control of Abbott caused or may cause a delay in completing the SEP, the parties will stipulate to an extension of time no longer than the period of delay.

c. If U.S. EPA does not agree that circumstances beyond the control of Abbott caused or may cause a delay in completing the SEP, U.S. EPA will notify Abbott in writing of its decision and any delays in completing the SEP will not be excused.

d. Abbott has the burden of proving that circumstances beyond its control caused or may cause a delay in completing the SEP. Increased costs for completing the SEP will not be a basis for an extension of time under subparagraph b, above. Delay in achieving an interim step will not necessarily justify or excuse delay in achieving subsequent steps.

Final Statement

104. This CAFO resolves only Abbott's liability for federal civil penalties for the violations alleged in the Alleged Violations section of this CAFO.

105. This CAFO does not affect the right of U.S. EPA or the United States to pursue appropriate injunctive or other equitable relief or criminal sanctions for any violation of law.

106. This CAFO does not affect Abbott's responsibility to comply with the Act and other applicable federal, state, and local laws and regulations. Except as provided in paragraph 104 above, compliance with this CAFO will not be a defense to any actions subsequently commenced pursuant to federal laws and regulations administered by U.S. EPA.

107. Abbott certifies that it is complying with the HON and Pharma-MACT.

108. This CAFO constitutes an “enforcement response” as that term is used in “U.S. EPA’s Clean Air Act Stationary Source Civil Penalty Policy” to determine Abbott’s “full compliance history” under Section 113(e) of the Act, 42 U.S.C. § 7413(e).

109. The terms of this CAFO bind Abbott, its successors, and assigns.

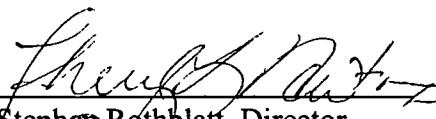
110. Each person signing this consent agreement certifies that he or she has the authority to sign this consent agreement for the party whom he or she represents and to bind that party to its terms.

111. Each party agrees to bear its own costs and attorneys’ fees in this action.

112. This CAFO constitutes the entire agreement between the parties.

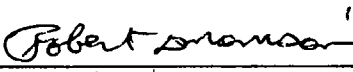
U.S. Environmental Protection Agency, Complainant

Date: 3/28/06

By: 
Stephen Rothblatt, Director
Air and Radiation Division
U.S. Environmental Protection
Agency, Region 5 (A-18J)

Abbott Laboratories, Respondent

Date: 3/23/06

By: 
Name: Robert D. Morrison
Title: VP Global Environment, Health, & Safety

CAA-05-2006-0018

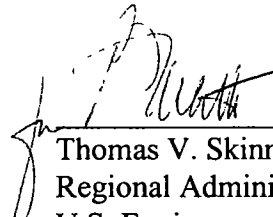
CONSENT AGREEMENT AND FINAL ORDER

Abbott Laboratories, North Chicago, Illinois

Docket No.

CAA-05-2006-0018 *LBW***Final Order**

It is ordered as agreed to by the parties and as stated in the consent agreement, effective immediately upon filing of this CAFO, with the Regional Hearing Clerk. This final order disposes of this proceeding pursuant to 40 C.F.R. § 22.18.

Date: 3-29-06

Thomas V. Skinner
Regional Administrator
U.S. Environmental Protection Agency
Region 5
77 West Jackson Boulevard
Chicago, Illinois 60604-3511

Certificate of Service

I, Shanee Rucker, certify that I hand delivered the original of the Consent Agreement and Final Order, docket number CAA-05-2006-0018, to the Regional Hearing Clerk, Region 5, United States Environmental Protection Agency, and that I mailed correct copies by first-class, postage prepaid, certified mail, return receipt requested, to Abbott and Abbott's counsel by placing them in the custody of the United States Postal Service addressed as follows:

Robert D. Morrison
Divisional Vice President
Abbott Laboratories
200 Abbott Park Road
Dept. 50D, Bldg. AP52S
Abbott Park, Illinois 60064-6212

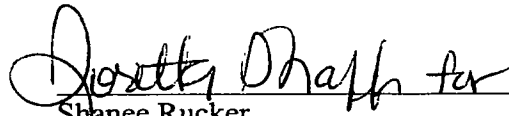
Hal Sprague
Abbott Laboratories
Legal Regulatory & Compliance
100 Abbott Park Road
Dept. 32RA, Bldg. AP6A-2NW
Abbott Park, Illinois 60064

US ENVIRONMENTAL
PROTECTION AGENCY
REGION V

6 MAR 30 P2:46

REGIONAL HEARING
CLERK

on the 30th day of March, 2006.


Shanee Rucker
AECAS (MI/WI)

CERTIFIED MAIL RECEIPT NUMBER: 7001 0320 0006 1447 9017 ~Morrison
7001 0320 0006 1447 9000 - Sprague